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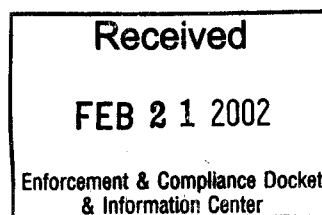
NORBERT DEE, Ph.D.
Director, Environmental Affairs

February 21, 2002

U.S. Environmental Protection Agency
Enforcement and Compliance Docket and Information Center
(Mail Code 2201 A)
Attn: Docket Number EC-2000-007
1200 Pennsylvania Ave., NW
Washington, DC 20460

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1200 Pennsylvania Avenue, NW,
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Subject: Comments of the National Petrochemical & Refiners Association (NPRA) on the proposed rule at 40 CFR Parts 3, 51, et al., "Establishment of Electronic Reporting: Electronic Records; published in the Federal Register on August 31, 2001.

The National Petrochemical & Refiners Association (NPRA) represents almost 500 companies, including virtually all US refiners and petrochemical manufacturers. Our members supply consumers with a wide variety of products and services that are used daily in homes and businesses. These products include gasoline, diesel fuel, home heating oil, jet fuel, asphalt products, and the chemicals that serve as "building blocks" in making everything from plastics to clothing to medicine to computers, etc.

In making and delivering products essential to everyone, our members work diligently to protect human health and the environment. That is why NPRA is a member of the Responsible Care® initiative, which requires continuous improvement in the health, safety, and environmental performance of processing facilities and products.

All of our petroleum refining and petrochemical members will be affected by the proposed rule. Electronic recordkeeping has become essential to normal business operations, as well as compliance with environmental and other governmental regulations. We are pleased to submit the attached comments on the proposed rule.

Sincerely,

Norbert Dee, Ph.D.

Director, Environmental Affairs

**Comments by the National Petrochemical & Refiners Association (NPRA)
on the Proposed Rule at 40 CFR Parts 3, 51, et al., Establishment of
Electronic Reporting: Electronic Records; Published in the Federal
Register on August 31, 2001
Submitted February 21, 2002**

1. NPRA supports the promotion and facilitation of electronic recordkeeping and reporting.

- Facility compliance recordkeeping requirements are so extensive that it has become necessary to utilize electronic means for those tasks.
- In the past ten years the use of computers has expanded dramatically, into virtually every aspect of our lives. Businesses, large and small, utilize computers for recordkeeping, computing, word processing, communications, etc.
- Computer systems will be used to an ever greater extent in the future. They have the benefits of speed, accuracy, reduced file storage space, and ease of recovery of information. For the benefit of all, we should be encouraging the maximum use of computer systems for recordkeeping and reporting.
- Some federal and state programs now require electronic recordkeeping and/or reporting.

2. NPRA supports electronic reporting; however, EPA should proceed carefully in promulgating rules for electronic reporting.

- The requirements for an acceptable electronic document to be submitted to EPA are straight-forward and reasonable. Section 3.10 of the proposed rule indicates an electronic document will satisfy the reporting requirement if "(1) The electronic document is submitted to an electronic document receiving system as provided under paragraph (b) of this section, and (2) The electronic document bears valid electronic signatures, as provided in paragraphs (c), (d) and (e) of this section, to the same extent that the paper submission for which it substitutes would bear handwritten signatures." However, reporting is primarily a concern for state and local agencies, which receive the bulk of reports by the regulated community. NPRA suggests that EPA should not make the requirements for those agencies so restrictive that it would discourage the use of electronic systems.

- The electronic reporting regulations must enable the use of electronic reports to substitute for paper reports required by the various environmental regulations.
 - Electronic reporting should not be more cumbersome than paper reporting, both for the regulated community and for the regulating agencies.
 - EPA has not anticipated the true cost for state and local environmental agencies to comply with the proposed rule, in order for those agencies to accept and utilize the electronic reports and data that they will be receiving. Consequently, many state and local agencies may choose to not accept electronic reporting.
- 3. EPA should withdraw the electronic recordkeeping portion of the proposed rule, and form an advisory workgroup to develop a new proposal, if in fact a recordkeeping rule is needed at all.**
- EPA has not recognized the extent to which the regulated community already utilizes electronic recordkeeping and reporting, and therefore has not presented an accurate picture of the burden associated with the rule as proposed. The agency's prediction of cost to the regulated community is based on the incorrect assumption that compliance with the rule would be voluntary.
 - The rule as proposed would not be voluntary as stated in the preamble. While electronic reporting, at the present time, would be voluntary for many regulated entities, electronic recordkeeping would not be voluntary. Virtually all facilities in the regulated community now use some form of electronic data collection and recordkeeping. Due to the large amount of data required by government regulations (in addition to normal business data) electronic methods are already integral to the collection and management of data by industry.

As a result, it is not "voluntary" to choose to use electronic recordkeeping. Today, facilities routinely use computers to collect information mandated by EPA. Realistically, information on emissions and effluent data can only be collected by computer. Many laboratory analyses are conducted using computer-based instruments. The large amounts of data which must be kept for reporting purposes or to meet recordkeeping requirements cannot be managed without the use of computers. This is true both for large and small facilities.

- The rule as proposed is unworkable, and will discourage rather than encourage the use of electronic recordkeeping. For example, CROMERRR reflects a decision by EPA to impose maximum security

protections on even the least important data requirements. This would have the effect of deterring, not encouraging, electronic recordkeeping, contrary to the purpose of the Government Paperwork Elimination Act (GPEA), and would be unacceptable in this "computer age."

Any rule governing electronic recordkeeping must be flexible enough to allow innovation in this rapidly changing electronic marketplace, and must allow facilities the flexibility to use the systems which best suit individual needs.

Whereas electronic reporting needs consistency, electronic recordkeeping needs flexibility. EPA should be careful to not become an impediment to the creative use of computers and other electronic systems.

- It is essential to base the rule on input from the regulated community, electronic hardware and software suppliers, state and local environmental agencies, as well as the program and enforcement offices of EPA.
- As stated in the preamble (66 FR 46169), "Regulated entities that use electronic systems to create, modify, maintain, or transmit electronic records will need to employ procedures and controls designed to meet the minimum criteria in today's rule." This presents several issues with current EPA regulations:

Many industrial facilities already use electronic systems to create electronic records that cannot be replaced with paper records. For example, Continuous Emission Monitoring Systems (CEMS) monitor and record stack concentrations of various air contaminants. The CEMS typically have some electronic data storage capability, but rely on transferring the data to other computer systems for long-term storage and report generation. Regulations already exist for many aspects of these data collection systems. Suspending the use of these systems until they can be "approved" by EPA appears contrary to the desire for improved continuous demonstration of compliance.

Leak detection and repair (LDAR) programs also rely extensively on electronic records. In order to comply with the extensive monitoring requirements in a large refinery or petrochemical complex, monitoring instruments that electronically record and transmit the data to computer reporting systems are necessary. It is not reasonable to require the regulated entities to monitor concentrations for tens of thousands of piping components on a quarterly basis, and then record all of the necessary data on paper. It would be very difficult to generate the required LDAR reports, on the required frequency, without using computer tools to manage the data.

- EPA has substantially underestimated the cost of the proposed rule, both to the regulated community and to the regulating agencies. Each facility now using a computer to keep EPA-mandated records would be subject to the proposed rule's electronic recordkeeping requirements upon promulgation. EPA's estimate of 428 facilities choosing to utilize electronic recordkeeping is far from reality, as noted in the previous comments. EPA found that costs would outweigh benefits based on only 428 facilities subject to the rule. Therefore, EPA's cost-benefit analysis severely under-estimates the true cost to industry, since, in reality, most of the 1.2 million facilities subject to EPA reporting requirements will be subject to the rule.

Currently the software does not exist to enable companies to comply with the rule as proposed. The preamble wording effectively prohibits the use of many current software tools, such as spreadsheets, that allow data to be more easily organized for reporting purposes. Software spreadsheets and databases, such as Microsoft Excel and Access which are used by "almost everyone," are not compliant. The proposed rule would require development prior to implementation, resulting in significant cost and dependency on a few software vendors. EPA's cost estimates do not address these compliance costs.

- The proposed rule was apparently patterned after a similar FDA rule at 21 CFR Part 11, issued in 1997. Companies subject to the FDA rule have found it to be mandatory (not voluntary), and significantly more costly than anticipated by the FDA. The preamble to the FDA rule also states that the recordkeeping provisions are voluntary, and that firms not confident that their electronic systems meet the minimal requirements of the regulations are free to continue to use paper documents to meet recordkeeping requirements. Yet, the preamble goes on to indicate that, in most cases, paper records created by computer would be considered electronic records covered by 21 CFR Part 11. EPA should not have used the FDA rule as a pattern. The industries regulated by EPA are different from those regulated by FDA. Consequently, recordkeeping requirements are different under EPA than under FDA. EPA should learn from the mistakes of the FDA experiment, but should not attempt to achieve consistency with the FDA rule.
- As noted previously, the regulated community currently utilizes extensive electronic recordkeeping according to the definition of "electronic record" in the proposed rule. Consequently, most regulated entities will be in immediate violation of the rule when promulgated, if the rule remains in its present form.
- The "audit trail" provisions are especially burdensome, and not needed for most recordkeeping. The preamble states "In general, EPA believes that

for electronic records to be trustworthy and reliable, their corresponding electronic record-retention system must: ...(6) use secure, computer-generated, time-stamped audit trails to automatically record the date and time of operator entries and actions that create, modify, or delete electronic records; (An audit trail is an important element of any acceptable electronic record, for it provides an electronic record of key entries and actions to a record throughout its life cycle. Such audit trail documentation needs to be retained for a period at least as long as that required for the subject electronic records. Audit trail documentation also needs to be available for agency review.)”

This section of the preamble, and the proposed rule section 3.100(a)(6), implies that every data element will require an audit trail. This significantly increases the amount of data that must be recorded and manipulated in an electronic system. As an example, in a modern refinery with a distributed control system (DCS), a data element such as fuel flow rate may be measured every few seconds. The DCS consolidates the individual data readings into time average values to minimize the number of data points that must be archived. If each individual data reading requires an audit trail, then the amount of data expands tremendously.

- In Section II C. of the preamble (page 46166 in the Federal Register) EPA poses the question: “*Why is EPA Proposing These Changes in Electronic Reporting Policy?*” EPA then provides the answer: “EPA is proposing these changes for three reasons. First, and most important, the technology environment has changed substantially since the September, 1996, policy was written.” And a few sentences later: “We could not have anticipated in 1996 that this evolution would occur as rapidly as it has.” Although this discussion refers to electronic reporting, it is equally true for electronic recordkeeping. Who can predict what electronic recordkeeping systems will look like five years from now? Any rule written to govern electronic recordkeeping must allow sufficient flexibility to encourage innovation and to allow systems to be designed for individual needs.

4. EPA seems overly concerned about the possibility for fraud in electronic recordkeeping.

- EPA has proposed to put more conditions on electronic recordkeeping than on paper recordkeeping.
- In the preamble to the proposed rule EPA lists three goals of the rulemaking, one of which reads: “To maintain or improve the level of corporate and individual responsibility and accountability for electronic reports and records that currently exists in the paper environment.”

First, the current recordkeeping environment is electronic and paper, not just paper, and EPA has not demonstrated a major problem with corporate and individual responsibility and accountability under the current system. Second, paper records rarely have any provision for audit trails and signatures. There will always be those few entities which attempt to cheat the system, and this fraud can be accomplished with paper records as easily as with electronic records. Third, there is no dispute over the requirement for reports submitted to a regulatory authority to have a valid signature of a responsible person. By signing such reports the signer assumes responsibility for the validity of the report and the supporting records. The agency, therefore, has a person to hold accountable for the veracity and accuracy of the reports and the records to back up the reports.

5. EPA has not complied with the Small Business Regulatory Enforcement Fairness Act (SBREFA).

Some NPRA members are in the small business category. It appears that EPA has not evaluated the effect of the rule on small businesses. As previously stated, most small businesses use electronic recordkeeping. EPA should conduct a regulatory flexibility analysis on the impact of CROMERRR recordkeeping requirements on small business.